

## Louisiana Medicaid Oncology Agents – Oral – Other

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request:

- Prior authorization for non-preferred oral other oncology agents
- Clinical authorization for selumetinib (Koselugo®)

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

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### Approval Criteria for Initial and Reauthorization Requests for Non-preferred Agents (Except Koselugo®)

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
  - The prescriber states that the recipient is currently using the requested medication; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

**Duration of initial and reauthorization approval:**

**Up to 12 months based upon patient-specific factors and the condition being treated.**

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## Selumetinib (Koselugo®)

### Approval Criteria

- The recipient is 2 years of age or older on the date of the request; **AND**
- The recipient has **BOTH** of the following and this is **stated on the request**:
  - Diagnosis of neurofibromatosis type 1 (NF1); **AND**
  - Symptomatic, inoperable plexiform neurofibromas (PN); **AND**
- Selumetinib (Koselugo™) is prescribed by, or the request states that this medication is being prescribed in consultation with, a neurologist; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

**Duration of initial authorization approval: 6 months**

### Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

**Duration of reauthorization approval: 12 months**

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### References

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.;  
<https://www.clinicalkey.com/pharmacology/>

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill;  
<https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861>

Koselugo (selumetinib) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2021. <https://www.azpicentral.com/koselugo/koselugo.pdf#page=1>

<b>Revision / Date</b>	<b>Implementation Date</b>
Single PDL Implementation	May 2019
Reviewed current criteria and no changes made / September 2019	January 2020
Separated “Oncology Agents” into individual therapeutic class documents / November 2019	January 2020
Add Koselugo® with reference, formatting changes, removed POS edit wording from document / July 2020	July 2020
Formatting changes, update references / September 2021	January 2022